REMARKS

In the Office Action mailed April 23, 2004, claims 1-3, 5-7, and 23-28 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office Action requested Applicants to specify the Shore level A-D present in the claims. In the present Amendment, Applicants have amended the claims so that they specifically call for values having a Shore A durometer hardness. Support for the claim amendments may be found on at least page 8, line 22 to page 9, line 5 of Applicants' application that disclose in one embodiment the valve member 42 made from a liquid injection molding silicone elastomer having product number MED-4810 manufactured by NuSil Technology. With the present Amendment, Applicants are providing the product profile of MED-4810 from NuSil Technology of Carpinteria, California that shows the durometer value of this material as being 10 Shore A. As such, Applicants' respectfully submit that the claims of the present application do not suffer from any §112 deficiencies.

Also in the Office Action of April 23, 2004, claims 1, 3, 5-7, and 28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Willis et al. (U. S. Patent No. 5,997,503) in view of Hillsted (U. S. Patent No. 4,798,594).

Claim 2 was rejected under 35 U.S.C. §103(a) as being unpatentable over Willis in view of Hillsted and further in view of Osbourne et al. (U.S. Patent Publication No. 0049501) or Copenhaver et al. (U. S. Patent No. 5,720,734).

Claims 23-27 were objected to under §112. In the present Amendment, Applicants have addressed any §112 deficiency with respect to claims 23-27 and as such respectfully submit that these claims are in condition for allowance.

Applicants respectfully submit that claim 1 defines over the combination of Willis and Hillsted. Respectfully, the combination of references do not disclose a valve member that is formed at least in part by a material having a durometer of less than 10 Shore A.

Willis does not disclose any information regarding the degree of hardness of the valve member (see page 3, lines 5-7 of the Office Action of 4/23/04). Hillsted discloses a hemostasis valve that includes an elastomeric partition made of an elastomer such as natural or synthetic latex that has a hardness value in the range of 30 to 50 Shore A durometer (see Hillsted at column 2, lines 39-43). As such, incorporation of the 30 to 50 Shore A durometer material of Hillsted into the catheter of Willis will not result in a valve member formed at least in part by a material having a durometer of less than 10 Shore A as set forth in claim 1 of Applicants' application. In order to establish a case of *prima facie* obviousness, the combination of references must teach or suggest all of the claim limitations. In this case, the combination of Willis and Hillsted will not result in a valve assembly that has a valve member formed at least in part by material having a durometer of less than 10 Shore A. Further, Hillsted actually teaches away from the use of a durometer value less than 10 Shore A by stating the preferred material is an oil-impregnated silicone rubber that has a durometer value of 40 (see Hillsted at column 4, lines 9-11). As such, the combination of Willis and Hillsted fails to disclose a durometer value of less than 10 Shore A and in fact teaches against a durometer value

of less than 10 Shore A by specifically teaching a range of 30 to 50 Shore A and a preferred value in the middle of the range at 40 Shore durometer.

As such, Applicants respectfully submit that independent claim 1 defines over the combination of Willis and Hillsted and is condition for allowance. Further, all claims that depend from claim 1 (claims 2, 3, and 5) are also in condition for allowance. Their rejection being made moot due to allowance of claim 1.

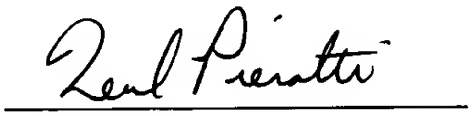
Claim 6 has been amended in order to call for a valve member that is formed at least in part by a material having a durometer value of less than 10 Shore A. Applicants respectfully submit that claim 6 defines over the combination of Willis and Hillsted for essentially the same reasons as discussed above with respect for claim 1 and is in condition for allowance. Further, all claims that depend from claim 6 (claims 7 and 28) are also in condition for allowance. Their rejections being made moot due to the allowance of claim 6.

With the present Amendment, Applicants submit that all pending claims are allowable and that the application is in condition for allowance. Favorable action thereon is respectfully requested.

The Examiner is encouraged to contact the undersigned at her convenience in order to resolve any remaining issues.

Respectfully submitted,

DORITY & MANNING, P.A.

By: 

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An ISO 9001 Certified Company

Product Profile

MED-4810

Liquid Injection Molding Silicone Elastomer

Description:

NuSil Technology MED-4810 Silicone Elastomer is a two-part, translucent, silicone system which is designed to be used with injection molding equipment. When properly cured, MED-4810 offers medium tear strength along with a 10 Shore A durometer. In addition it has good electrical properties and an operating temperature range of -65°C to 250°C (-85°F to 484°F).

The benefits of this material include:

- Rapid Cure
- Post-cure not required
- Less yellowing with aging
- Increased efficiency over transfer molding

Applications:

MED-4810 is designed for applications requiring a 10 Shore A durometer. Some typical applications include potting and encapsulating of electronic devices and molded parts where a soft high strength material is desirable.

Mixing:

MED-4810 Part A and Part B are supplied in a convenient 1:1 mix ratio for use with automatic mix and dispense equipment. If mixing is to be done by hand, care should be taken to minimize air entrapment during mixing.

Vacuum Deaeration:

Air entrapped during mixing should be removed by common vacuum deaeration procedure, observing all applicable safety precautions. Apply full vacuum slowly to a container rated for use and of volume at least four times the volume of material to be deaerated. Hold vacuum until bulk deaeration is complete.

Typical Properties as Supplied:

	MED-4810
Extrusion Rate, gpm	40
Chemical Classification	VMQ
Color	Translucent
Viscosity, cps Part A	600,000
Viscosity, cps Part B	500,000
Working Time (curing agent added), hours	6
Mix Ratio (by weight)	1:1

Typical Properties:

Cured 5 min @ 150°C (302°F)

	MED-4810
Specific Gravity @ 25°C (77°F)	1.07
Durometer, Shore A	10
Tensile Strength, psi / MPa	900 / 6.2
Elongation, %	1200
Tear Strength, ppi. Die B / kN/m	75 / 13.1
Stress @ 200%, psi / Mpa	45 / .1

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Typical Cure Schedule:

Temperature °C (°F)	Cure Time
25C° (77F°)	Not Recommended
100C° (212F°)	30 Minutes
150C° (302F°)	5 Minutes

Cure rates are largely dependent on mold configuration and part size.

Test Methods:

	ASTM	NTM
Specific Gravity	D792	003
Durometer Hardness	D2240	006
Tensile Strength, psi	D412	007
Elongation, percent	D412	007
Tear Strength	D624	009
Stress @ 100%, psi	D412	007

Substrate Considerations:

MED-4810 will cure in contact with most materials. Exceptions include sulfur cured organic rubbers, latex, chlorinated rubbers, some RTV silicones and unreacted residues of some curing agents.

Packaging:

Slab
Fifty ML Side by Side Kit
Two Pint Kit
Two Drum Kit

FDA Master File:

A Master File for MED-4810 will be filed with the U.S. Food and Drug Administration. The Master File will contain the results of applicable chemical and mechanical equivalency tested as well as confirmatory biological testing. Customers interested in authorization to reference these files must contact NuSil Technology.

Warnings About Product Safety:

NuSil Technology believes that the information and data contained herein is accurate and reliable; however, it is the user's responsibility to determine suitability and safety of use for these materials. NuSil Technology can not know the specific requirements of each application and hereby makes the user aware that is has not tested or determined that these materials are suitable or safe for any application. It is the user's responsibility to adequately test and determine the safety and suitability for their application and NuSil Technology makes no warranty concerning fitness for any use or purpose. There has been no testing done by NuSil Technology to establish safety of use in any medical application.

NuSil Technology has tested this material only to determine if the product meets the applicable specifications. (Please contact NuSil Technology for assistance and recommendations when establishing specifications.) When considering the use of NuSil Technology products in a particular application, you should review the latest Material Safety Data Sheets and contact NuSil Technology for any questions about product safety information you may have.

No chemical should be used in a food, drug, cosmetic, or medical application or process until you have determined the safety and legality of the use. It is the responsibility of the user to meet the requirements of the U.S. Food and Drug Administration (FDA) and any other regulatory agencies. Before handling any other materials mentioned in the text, you should obtain available product safety information and take the necessary steps to ensure safety of use.

Specifications:

The typical properties shown in this technical profile should not be used as a basis for preparing specifications. Please contact NuSil Technology for assistance and recommendations in establishing particular specifications.

Patent Warning:

NuSil Technology disclaims any expressed or implied warranty against the infringement of any patent. NuSil Technology does not warrant that the use or sale of the products described herein will not infringe the claims of any United States patents or other country's patents covering the product itself or the use in combination with other products or in the operation of any process.

Warranty Information:

NuSil Technology's warranty period is 6 months from date of shipment when stored below 40°C in

original unopened containers. Unless NuSil Technology provides you with a specific written warranty of fitness for a particular use, NuSil Technology's sole warranty is that the product will meet NuSil Technology's then current specification. NuSil Technology specifically disclaims any other express or implied warranty, including warranties of merchantability and of fitness for use. Your exclusive remedy and NuSil Technology's sole liability for breach of warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted, and NuSil Technology expressly disclaims any liability for incidental or consequential damages.

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